Withdrawn Rejections

Applicant acknowledges that the 35 USC § 112 1st paragraph rejection has been withdrawn.

Claim Rejections - 35 USC §103

The Examiner Claims 1-8 are rejected under 35 U.S.C. 103(a) allegedly as being unpatentable over Rockich et al. (Research Report presented at the annual meeting of the American Association of Pharmaceutical Scientists, Boston, MA, 1432-1436, 1997 (cited in IDS and response 3/15/07)) and Hitoshi et al., (Brain Injury, Vol. 14, No. 7, 669-676, 2000 (cited in IDS and response 3/15/07)).

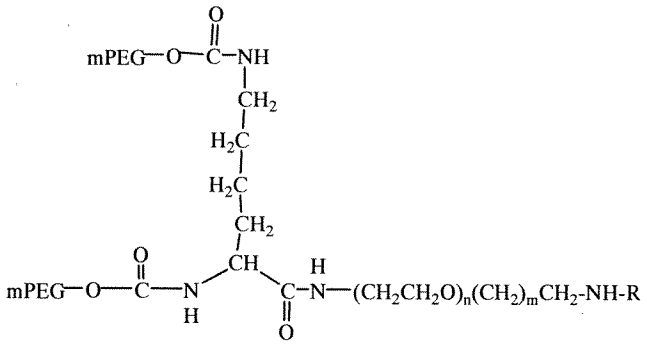
The Examiner refers to the factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The Examiner asserts that not only did the Applicant's argument and the cited references not previously of record overcome the previous rejection under USC §112 1st paragraph it provided above "reasonably correlate[ed]" between the activity in question and the asserted utility to the level of rendering obvious the presently claimed invention. The Examiner alleges the only difference between the prior art and the claims at issue appears to be the use of a pegylated form of hGH (Applicant's Formula I) rather than a recombinant or native form of hGH as in the references? And whether it would have been obvious to select the former in place of the latter? The Examiner asserts that the selection of ANY known hGH, including pegylated (like that of Applicant's Formula I), at the time of the invention for "treating" TBI with some "benefit" would have been merely a matter of routine optimization by one of ordinary skill in the art, depending on the cost/access to said form of hGH and the desired outcome of treatment (e.g. longer duration form).

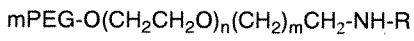
Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness based on the proper factual inquiries set forth in

Graham. The claimed invention is not directed to the treatment of Traumatic Brain Injury or Subarachnoid Haemorrhage using ANY pegylated-hGH conjugate but rather the pegylated-hGH conjugate of the Formula I or II.



Formula I

or



Formula II

wherein

n is an integer between 1 and 10;

m is an integer between 1 and 10;

A proper *prima facie* case of obviousness must show that **every element** is found in the prior art. The Examiner freely concedes in the previous Office Action that a very broad search of the prior art (EAST) database for the use of hGH in the same paragraph as traumatic brain injury or subarachnoid hemorrhage, *using the present compound Formula 1 compound*, yielded only Applicant's present published specification. Rockich et al. and Hitoshi et al. do not teach the pegylated-hGH conjugate of the Formula I or II. While the prior art made of record and not relied upon by the Examiner (WO 93/00109 and Clark et al. (J Biol Chem. 1996; 271(36):21969-77) may teach PEGylated forms of hGH it does **not** teach the pegylated-hGH conjugate of the Formula I or II. Therefore treatment of Traumatic Brain Injury or Subarachnoid Haemorrhage using the pegylated-hGH conjugate of the Formula I or II is non-obvious.

Applicant also asserts that the rejection is a new rejection and accordingly the Examiner making the rejection FINAL is improper. Applicant submits that the additional references cited in the IDS submitted 03/15/2007 are only corroborative of the prior art already of record (**C10** of IDS filed August 23, 2006 (Kelly, D.F., *J.*

Neurosurg 93:743-572, 2000; **C8** Aimaretti, G., et al., *The Journal of Clinical Endocrinology & Metabolism*, 90(11) 6085-6092,2005; **C9** Aimaretti, G., et al., *Clinical Endocrinology*, 61: 320-326, 2004; **C11** Kreitschmann-Andermahr, I., et al., *The Journal of Clinical Endocrinology & Metabolism*, 89(10) 4986-4992, 2004) and were submitted to further refute the Examiner's false impression that there was not a reasonable correlation between traumatic brain injury and hGH. The Examiner could have made the same rejection, in all still an improper *prima facie* case of obviousness, based on the art of record. Therefore, applicant request that the finality of the action be withdrawn, the amendment be entered and the Examiner reconsider the rejection.

Conclusion

In view of the foregoing, it is respectfully submitted that all claims now pending in the present application are in condition for allowance. Therefore, passage of the application and claims to issue is respectfully requested.

Respectfully submitted,

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